DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2004 Budget Request

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement by

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on
FY 2004 President's Budget Request
for the Office of the Director

Mr. Chairman, Members of the Committee:

I am pleased to present the President's budget request for the Office of the Director (OD) for FY 2004, a sum of $317,983,000, which reflects an increase of $44,031,000 over the comparable FY 2003 appropriation. The OD provides leadership, coordination, and guidance in the formulation of policy and procedures related to biomedical research and research training programs. The OD also is responsible for a number of special programs and for management of centralized support services to the operations of the entire NIH.

The OD guides and supports research by setting priorities; allocating funding among these priorities; developing policies based on scientific opportunities and ethical and legal considerations; maintaining peer review processes; providing oversight of grant and contract award functions and of intramural research; communicating health information to the public; facilitating the transfer of technology to the private sector; and providing fundamental management and administrative services such as budget and financial accounting, and personnel, property, and procurement management, administration of equal employment practices, and plant management services, including environmental and public safety regulations of facilities. The principal OD offices providing these activities include the Office of Extramural Research

(OER), the Office of Intramural Research (OIR), and the Offices of: Science Policy; Communications and Public Liaison; Legislative Policy and Analysis; Equal Opportunity; Budget; and Management. This request contains funds to support the functions of these offices.

In addition, the OD also maintains several trans-NIH offices and programs to foster and encourage research on specific, important health needs; I will now discuss the budget request for each of these trans-NIH offices in greater detail.

THE OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH Institutes and Centers. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. Each year, OAR oversees the development of the comprehensive NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The Plan serves as the framework for developing the annual AIDS research budget for each

Institute and Center; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. OAR identifies scientific areas that require focused attention and facilitates multi-institute activities to address those needs. OAR coordinates, monitors and fosters plans for NIH involvement in international AIDS research and training activities. OAR supports a number of initiatives to enhance dissemination of research findings to researchers, physicians, patients and communities. The FY 2004 budget request for OAR is $60,942,000.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH) serves as the focal point for women's health research for the Office of the Director, to ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by the NIH, and to develop and support biomedical careers. The report, *An Agenda for Research on Women's Health for the 21st Century*, provides the basis for the ORWH to collaborate with the scientific and advocacy communities to address scientific initiatives about women's health and sex and gender factors in health and disease. In FY 2004, the OD budget request of $41,231,000 includes an increase of $808,000 over the FY 2003 enacted budget of $40,423,000 for the ORWH to continue stimulating new research and to implement innovative career development programs.

Research priorities for women's health emphasize the importance of interdisciplinary collaboration, especially for chronic, multi-systemic conditions; prevention and elimination of high risk behaviors, such as overeating and physical

inactivity, which contribute to morbidity and premature mortality of women; and reproductive health, including such gynecologic conditions as uterine fibroid tumors, and further exploring issues related to the menopausal transition, such as hormone therapy. The ORWH continues to partner with Institutes and Centers to monitor compliance with NIH policies for the inclusion of women and minorities in clinical research, and to ensure that analyses by sex/gender are addressed. The ORWH is witnessing exciting expansion of new research in its specialized centers of interdisciplinary research in women's health and sex and gender factors. The ORWH has also expanded its unique interdisciplinary career development program in women's health research that fosters the mentored development of junior faculty and assists them in bridging advanced training for junior investigators with research independence. In addition, the ORWH has now implemented a new Intramural Program on Research on Women's Health to focus on NIH intramural women's health and sex and gender comparison research.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The NIH has a long history of funding health-related behavioral and social sciences research, and the results of this work have contributed significantly to our understanding, treatment, and prevention of disease. The Office of Behavioral and Social Sciences Research (OBSSR) furthers NIH's ability to capitalize on the scientific opportunities that exist in behavioral and social sciences research by providing leadership in identifying and implementing research programs in behavioral and social sciences that are likely to improve our understanding of the processes underlying health and disease and provide

directions for intervention. OBSSR works to integrate a behavioral and social science approach across the programs of the NIH. The FY 2004 OD budget includes $26,179,000 for OBSSR, an increase of $513,000 over the FY 2003 appropriation.

Many exciting scientific developments are occurring at the intersection of behavioral and social science research and biomedical research. OBSSR and several ICs are in the process of developing new approaches to train individuals to undertake a program of research that extends well beyond traditional disciplinary boundaries. One such initiative is a new postdoctoral program that would provide individuals trained in one discipline with formal course work and hands-on training in a second field. Collaboration between social and behavioral scientists and biomedical investigators is still relatively uncommon, in part, because traditionally trained social and behavioral researchers lack sufficient expertise in the biomedical fields and vice versa. The initiative will provide a mechanism for training investigators to work in interdisciplinary teams to tackle some of our most pressing health problems.

OBSSR is also developing an initiative that will encourage investigators to expand on the current theoretical base of change processes and intervention models, to expand our understanding of how change, once achieved, is maintained over the long term. Maintaining behavior change over the long term appears as challenging, if not more so, than the initiation of behavior change. Past research efforts have typically focused on short-term behavioral change. However, other research indicates that relapse rates for

addictive behaviors such as substance abuse and tobacco use are very high. Additionally, while the positive association between education and health has been well documented, there is a paucity of scientific information on the biological mechanisms and the causal pathways that underpin this association. OBSSR in collaboration with other ICs issued a Request for Applications to increase extramural research activity on this important scientific question.

THE OFFICE OF DISEASE PREVENTION

The primary mission of the Office of Disease Prevention (ODP) is to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other federal agencies as well as the private sector. There are several other offices within the ODP organizational structure.

The Office of Medical Applications of Research (OMAR) has as its mission to work with NIH Institutes, Centers, and Offices to assess, translate and disseminate the results of biomedical research that can be used in the delivery of important health services to the public. The Office of Disease Prevention (ODP) has several specific programs/offices that strive to place new emphasis on the prevention and treatment of disease.

In FY 2004, the Office of Dietary Supplements (ODS) within ODP requests a budget of $18,778,000. It will continue to promote the scientific study of the use of dietary supplements by

supporting investigator-initiated research in conjunction with other ICs at NIH and stimulating research through conduct of conferences and through presentations at national and international meetings. In its continuing efforts to inform the public about the benefits and risks of dietary supplements, the ODS expanded the International Bibliographic Information on Dietary Supplements (IBIDS) database to include a consumer-oriented search strategy. It has also disseminated a database devoted to federal funding of dietary supplement research, called CARDS, which is currently populated with data about the NIH investment from FY 1999-2001. ODS publishes Fact Sheets about vitamin and mineral dietary supplements in collaboration with the NIH Clinical Center, as well as Fact Sheets about botanical supplements in conjunction with the National Center for Complementary and Alternative Medicine. ODS, in collaboration with the National Heart Lung and Blood Institute and other NIH ICs, has sponsored a systematic review of the relationship between omega-3 fatty acids and a series of clinical indications, particularly coronary heart disease. Several reports will be published in FY 2003 and FY 2004 based upon this review, which will serve as the basis for planning further NIH research on omega-3 fatty acids. To determine the future research studies of efficacy and safety of dietary supplements containing ephedra, ODS sponsored a systematic review of ephedra efficacy and safety, which has recently been completed. ODS has initiated work on a pre-clinical study of ephedra by the National Toxicology Program. Congressional language in the FY 2002 and FY 2003 appropriation reports directed ODS to enhance an ongoing collaboration for the development, validation, and dissemination of analytical methods and reference materials for botanical dietary supplements. ODS works with other partners in the public and private sectors to meet this objective. **ODS supports the National Health and Nutrition Examination Survey (NHANES), conducted by the National Center for Health Statistics at the Centers for**

Disease Control and Prevention, in order to provide more information about dietary supplement use in the US population. This will inform future research about potentially important target populations, such as children, women, and the elderly. Funding is used to create and populate a database of dietary supplements, as well as to support the measurement of blood levels of key metabolites associated with dietary supplement use. In FY 2003, ODS and USDA published the proceedings of a workshop that examined the emerging needs for dietary assessment, including supplement use, in national surveys such as NHANES. A key outcome has been to develop an analytically-based database of dietary supplement ingredients.

Another component of ODP, the Office of Rare Diseases (ORD), develops and disseminates information to patients and their families, health care providers, patient support groups, and others and forges links among investigators with ongoing research activities in this area. The ORD supports workshops and symposia to stimulate research on rare diseases.

To provide better and faster information, ORD, together with the National Human Genome Research Institute (NHGRI), established the Genetic and Rare Diseases Information Center to respond to requests for information about genetic and rare disorders. The FY 2004 budget request for ORD is $11,423,000.

The ORD, supports together with NIH Institutes and Centers research on rare diseases. Approximately 25 million people in the United States are affected by an estimated 6,000 rare diseases. A 'rare disease' is defined as a condition affecting fewer than 200,000 Americans. On

November 6, 2002, the President signed the Rare Diseases Act of 2002 (P.L.107-280). The purposes of this Act are to establish the Office of Rare Diseases in statute at the National Institutes of Health and to increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.

THE OFFICE OF SCIENCE EDUCATION

The Office of Science Education (OSE) plans, develops, and coordinates science education programs to strengthen and enhance efforts of the NIH to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children. The office's mission is to help people *understand* and *use* new knowledge uncovered by the NIH in pursuit of better health for everyone. The OSE works toward this mission by: creating programs to improve science education in schools (the *NIH Curriculum Supplement Series*); creating programs that stimulate interest in health and medical science careers (*the new LifeWorks Web site)*; creating programs to advance public understanding of medical science, research, and careers; promoting NIH educational resources and programs; and advising NIH leadership about science education issues. All office programs target diverse populations including under-served communities, women, and minorities, with a special emphasis on the teachers of students from Kindergarten through grade 12. The OSE works closely with NIH institutes, centers, and offices on science education issues, and maintains the OSE Web site as a source of information about available resources and programs. http://science.education.nih.gov/.

The NIH Curriculum Supplements series are *National Science Education Standards*-based lesson plans that are distributed free to K-12 teachers across the country. **They incorporate the best of both science and education communities, and are intended to update science content and allow the teacher to incorporate the latest NIH research into classroom instructions.** ***Life Works*** **is a new OSE Web site created as a source of career information for students, teachers, counselors, and parents. The site will allow exploration of the educational requirements, knowledge, skills, and abilities required for over 100 health and medical science careers. The FY 2004 Budget request for OSE is $3,866,000.**

LOAN REPAYMENT AND SCHOLARSHIP PROGRAM

The NIH, through the Office of Loan Repayment and Scholarship (OLRS), administers the Loan Repayment and Undergraduate Scholarship Programs. The NIH Loan Repayment Programs (LRPs) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees to biomedical and behavioral research careers by countering the growing economic disincentives to embark on such careers, using as an incentive the repayment of educational loans. There are loan repayment programs designed to attract individuals to clinical research, pediatric research, health disparities research, and contraception and infertility research, and to attract individuals from disadvantaged backgrounds into clinical research. The AIDS, Clinical, and General Research Loan Repayment Programs are designed to attract investigators and physicians to the NIH's intramural research and research training programs. The NIH Undergraduate Scholarship Program (UGSP) is a scholarship program designed to support

the training of undergraduate students from disadvantaged backgrounds in biomedical research careers and employment at the NIH. The FY 2004 Budget request for OLRS is $6,843,000.

NIH ROADMAP

The NIH Director is taking an innovative approach to accelerate fundamental discovery and translation of that knowledge into effective prevention strategies and new treatments–an effort referred to as the NIH Roadmap. The FY 2004 budget request for the Office of the Director includes an increase of $35,000,000 for strategic "roadmap" initiatives. These funds will be allocated by the NIH Director to the Institutes and Centers to address critical roadblocks and knowledge gaps that currently constrain rapid progress in biomedical research. Three broad initiatives will be stimulated with these funds: 1) new pathways to discovery, which includes a comprehensive understanding of building blocks of the body's cells and tissues and how complex biological systems operate, regenerative medicine, structural biology, molecular libraries, nanotechnology, bioinformatics and computational biology, and molecular imaging; 2) research teams of the future, including multidisciplinary research and public-private sector partnerships; and 3) re-engineering the clinical research enterprise. These efforts will allow the NIH to rethink the infrastructure that is required to translate findings from the genomic era into front-line treatments and prevention strategies that benefit people in this country and abroad..

Thank you for giving me the opportunity to present this statement; I will be pleased to answer questions.